UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

JANET CANARY,

Plaintiff,

v.

MEDTRONIC, INC.,

Defendant.
_____/

Case No. 16-11742

Honorable Nancy G. Edmunds

OPINION AND ORDER GRANTING IN PART DEFENDANT'S MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT [17]

In May of 2013, Plaintiff was implanted with a spinal cord stimulator manufactured by Defendant Medtronic, Inc. Within a few days after this device was activated, Plaintiff allegedly developed a severe allergic reaction and hives over her entire body, and she was admitted to an intensive care unit at a local hospital. It was soon determined that Defendant's device had triggered Plaintiff's allergies to latex and rubber, and the device was removed in June of 2013. Based on this incident, Plaintiff has asserted state-law product liability and fraud claims against Defendant, alleging that Defendant's medical device had manufacturing and design defects, that Defendant failed to provide adequate warnings against the alleged defects in its device, and that Defendant's representatives made misrepresentations to Plaintiff about the safety of Defendant's medical device.

Through the present motion filed on January 3, 2017, Defendant seeks the dismissal of Plaintiff's first amended complaint under Federal Rule of Civil Procedure 12(b)(6).[1] In

[1]Defendant previously filed a motion to dismiss Plaintiff's initial complaint, but this motion was resolved through a stipulated order authorizing Plaintiff to amend her

support of this motion, Defendant argues that Plaintiff's product liability claims are preempted by federal law, either expressly or by implication, and that Plaintiff also has failed to adequately plead her state-law claims of product liability and fraud.

On April 12, 2017, the Court heard oral argument on Defendant's motion. For the reasons stated more fully below, the Court GRANTS IN PART AND DENIES IN PART Defendant's motion to dismiss, holding that Plaintiff's product liability claims are expressly preempted but that she may go forward with her claim of fraud.

I. FACTS

The facts giving rise to this suit are set forth in Plaintiff's first amended complaint, and Plaintiff's factual allegations are accepted as true for present purposes. Defendant Medtronic, Inc. designs, manufactures, markets, and sells a variety of medical devices, including the PrimeAdvanced spinal cord stimulator at issue in this case. This product is deemed a Class III medical device under federal law, and Defendant therefore had to secure the approval of the federal Food and Drug Administration ("FDA") before it could market and sell this device. *See* 21 U.S.C. § 360c(a)(1)(C)(ii).[2]

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complaint.

[2]According to public records accompanying Defendant's motion, Defendant obtained premarket approval for a predecessor spinal cord stimulator back in 1984, and the FDA granted premarket approval of the specific device involved in this case on July 7, 2006. (*See* Defendant's Motion, Ex. 1 (record of premarket approval of predecessor device); Ex. 2 (record of premarket approval of device implanted in Plaintiff).) As Defendant observes, although the records evidencing the FDA's approval of Defendant's device are not part of the pleadings in this case, the Court "may consider public records without converting a Rule 12(b)(6) motion into a Rule 56 [summary judgment] motion." *Jones v. City of Cincinnati,* 521 F.3d 555, 562 (6th Cir. 2008); *see also Thorn v. Medtronic Sofamor Danek, USA, Inc.,* 81 F. Supp.3d 619, 622-23 (W.D. Mich. 2015) (considering a medical device's premarket approval and its FDA-approved label in deciding a motion to dismiss).

In February of 2008, Plaintiff Janet Canary was involved in a motor vehicle accident and sustained serious injuries to her spine. Over the next few years, Plaintiff underwent a number of fusion surgeries to address these injuries. Following these surgeries, Plaintiff's physicians recommended that she consider the implantation of a permanent spinal cord stimulator to address her chronic neck and back pain.

As Plaintiff decided whether to pursue this course, she met on multiple occasions with her doctors and one of Defendant's representatives, identified in the complaint as "Violet." The first such meeting was held on June 11, 2012, and Plaintiff alleges that she informed Violet on this occasion that "she had a latex and rubber allergy" and had experienced "allergic reactions to materials used in [her] previous fusion surgeries." (First Amended Complaint at ¶ 18.) Plaintiff asserts that she also disclosed these allergic reactions in a questionnaire provided to Defendant at this meeting. When Plaintiff asked Defendant's representative, Violet, whether "other patients have had allergic reactions to any of the manufacturing materials and/or components in [Defendant's] spinal cord stimulators," Violet responded that no patients had experienced such an allergic reaction, and she assured Plaintiff that "a latex and rubber allergy did not prevent implantation of [Defendant's] spinal cord stimulators." (*Id.* at ¶ 21.)

Based on these representations, Plaintiff agreed to a trial use of Defendant's spinal cord stimulator, and a physician implanted this trial device on October 11, 2012. In contrast to a permanent implant, the majority of the trial device remained outside of Plaintiff's body. Although Plaintiff did not experience any allergic reactions during this trial, she notes that the trial device "was only activated for less than six hours," and was "implanted for less than 24 hours because it was accidentally pulled out of her back during the trial." (*Id.* at ¶ 23.)

Plaintiff next met with her physician and Defendant's representative, Violet, on April 24, 2013. Plaintiff again inquired about other patients who might have had allergic reactions to the materials used in Defendant's spinal cord stimulators, and Violet again responded that there had been no such allergic reactions, and that a latex or rubber allergy would not preclude the implantation of Defendant's spinal cord stimulators. (*See id.* at ¶ 24.) Accordingly, Plaintiff elected to go forward with the implantation of a permanent spinal cord stimulator, and this procedure was scheduled for May 16, 2013.

On the date of this procedure, Plaintiff met once more with her physician and Defendant's representative, Violet. After Violet once again confirmed that no patients had reported allergic reactions to the materials used in Defendant's spinal cord stimulators and that latex and rubber allergies were no barrier to the use of this device, Plaintiff went ahead with the permanent implantation of Defendant's PrimeAdvanced spinal cord stimulator.

On May 22, 2013, Plaintiff's physician activated the device that had been implanted a few days earlier. Within five hours, Plaintiff developed pruritus at the site of the device's lead and battery placement, and "[o]ver the next four days, she . . . developed hives over her entire body." (*Id.* at ¶ 28.) This allergic reaction got progressively worse over the next few days, to the point that Plaintiff was admitted to the intensive care unit at a local hospital from May 28 to May 31, 2013. Upon her discharge from the hospital, Plaintiff was diagnosed with "contact dermatitis secondary to spinal cord stimulator with resulting urticaria and pruritus." (*Id.* at ¶ 34.)

While Plaintiff was in the midst of this severe allergic reaction, she called Defendant's representative, Violet, on May 26, 2013 and informed her of the various conditions from which she was suffering following the activation of Defendant's device, including "a fever,

vomiting, difficulty breathing, swelling of her hands and face," and an outbreak of hives over her entire body. (*Id.* at ¶ 29.) In response, Violet "only then informed [Plaintiff] that other . . . patients had indeed [experienced] allergic reactions to manufacturing materials and/or components of [Defendant's] spinal cord stimulator, which included being covered in hives." (*Id.*) More specifically, Plaintiff alleges that Defendant's device "contained latex and/or rubber manufacturing materials and/or components," and that Defendant's representative, Violet, was aware prior to the date of Plaintiff's procedure that other patients had suffered allergic reactions to these substances in Defendant's device. (*Id.* at ¶¶ 30-31.)

On June 13, 2013, Plaintiff underwent another procedure to remove Defendant's device, and her physician subsequently informed her that another such device could not be implanted due to her latex and rubber allergies. Since her allergic reaction to Defendant's device, Plaintiff continues to suffer from a variety of symptoms, including dermographism and hypersensitivity to products containing certain plastics, rubber, and latex. In this suit, Plaintiff now seeks to recover for these injuries under three state-law theories of product liability — manufacturing defect, design defect, and failure to warn — and she also asserts a state-law claim of fraud arising from Defendant's alleged misrepresentations that its spinal cord stimulator was safe for use by patients with known latex and rubber allergies.

II. STANDARD OF REVIEW

Through its present motion, Defendant seeks the dismissal under Fed. R. Civ. P. 12(b)(6) of each of the claims asserted in Plaintiff's first amended complaint. When determining whether Plaintiff's claims are subject to dismissal under Rule 12(b)(6) for failure to state a claim, the Court must construe the complaint in a light most favorable to

Plaintiff and accept all well-pleaded factual allegations as true. *League of United Latin American Citizens v. Bredesen*, 500 F.3d 523, 527 (6th Cir. 2007). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949 (2009).

Moreover, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964-65 (2007) (internal quotation marks, alteration, and citations omitted). Rather, to withstand a motion to dismiss, the complaint's factual allegations, accepted as true, "must be enough to raise a right to relief above the speculative level," and to "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 555, 570, 127 S. Ct. at 1965, 1974. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678, 129 S. Ct. at 1949.

The Supreme Court has emphasized that this plausibility standard "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678, 129 S. Ct. at 1949. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged — but it has not shown — that the pleader is entitled to relief." *Iqbal,* 556 U.S. at 679, 129 S. Ct. at 1950 (internal quotation marks, alteration, and citation omitted). If a plaintiff does "not nudge[] [her] claims across the line from conceivable to

plausible, [her] complaint must be dismissed." *Twombly*, 550 U.S. at 570, 127 S. Ct. at 1974.

III. ANALYSIS

A. Plaintiff's Product Liability Claims Are Expressly Preempted by Federal Law.

1. The Law Governing Defendant's Preemption Challenge

As the principal argument advanced in its motion, Defendant contends that Plaintiff's state-law product liability claims are preempted by federal law, either expressly or by implication. Before turning to the specific claims of preemption raised by Defendant in this case, the Court finds it instructive to survey the law that governs this inquiry.

As the Supreme Court has observed, the federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.,* has "long required FDA approval of the introduction of new drugs into the market," but until the 1970s, "the introduction of new medical devices was left largely for the States to supervise as they saw fit." *Riegel v. Medtronic, Inc.,* 552 U.S. 312, 315, 128 S. Ct. 999, 1002 (2008). This legal landscape changed with the enactment of the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq.,* "which swept back some state obligations and imposed a regime of detailed federal oversight." *Riegel,* 552 U.S. at 316, 128 S. Ct. at 1003. The "new regulatory regime" ushered in through the MDA "established various levels of [FDA] oversight for medical devices, depending on the risks they present," with Class I devices "subject to the lowest level of oversight" and Class III devices receiving the most stringent regulatory scrutiny. 552 U.S. at 316-17, 128 S. Ct. at 1003.

The spinal cord stimulator at issue here is a Class III device, and it therefore was

subject to "a rigorous regime of premarket approval" before it could be sold. 552 U.S. at 317, 128 S. Ct. at 1004. To secure this approval, a manufacturer "must submit what is typically a multivolume application" that "includes, among other things," (i) "full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant," (ii) a "full statement of the device's components, ingredients, and properties" and its "principles of operation," (iii) a "full description of the methods used in, and the facilities and controls used for, the manufacture [and] processing" of the device, and (iv) "a specimen of the proposed labeling" of the device. 552 U.S. at 317-18, 128 S. Ct. at 1004 (internal quotation marks and citation omitted). "The FDA spends an average of 1,200 hours reviewing each application" for premarket approval of a Class III device, and "grants premarket approval only if it finds there is a reasonable assurance of the device's safety and effectiveness." 552 U.S. at 318, 128 S. Ct. at 1004 (internal quotation marks and citation omitted). In conducting this inquiry, the agency "must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," and this cost/benefit analysis may lead to the approval of "devices that present great risks if they nonetheless offer great benefits in light of available alternatives." 552 U.S. at 318, 128 S. Ct. at 1004 (internal quotation marks and citation omitted).

"Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." 552 U.S. at 319, 128 S. Ct. at 1005. "If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval,

to be evaluated under largely the same criteria as an initial application." 552 U.S. at 319, 128 S. Ct. at 1005.

Beyond setting forth these detailed standards for FDA approval of medical devices, the MDA also includes an express preemption provision:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).[3] This provision has been construed as "establish[ing] a two-prong test for determining if a state-law tort claim is preempted." *Hughes v. Boston Scientific Corp.,* 631 F.3d 762, 767 (5th Cir. 2011). First, the Court must "determine whether the Federal Government has established requirements applicable to" the particular device at issue. *Riegel,* 552 U.S. at 321, 128 S. Ct. at 1006. If so, the Court then must inquire whether Plaintiff's product liability claims "are based upon [state-law] requirements with respect to [Defendant's] device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." 552 U.S. at 321-22, 128 S. Ct. at 1006 (quoting 21 U.S.C. § 360k(a)).

2. Plaintiff's Conclusory Allegations of Violations of FDA Regulations Fail to Save Her Product Liability Claims from Federal Preemption.

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[3]As observed by the Supreme Court, "[t]he exception contained in subsection (b) [of this provision] permits the FDA to exempt some state and local requirements from pre-emption." *Riegel,* 552 U.S. at 316, 128 S. Ct. at 1003.

Against this legal backdrop, the Court turns to the specific claim of express preemption advanced in Defendant's motion. The parties agree as to certain elements of this preemption inquiry. First, it is undisputed that Defendant's spinal cord stimulator received the requisite FDA approval applicable to Class III devices. As noted earlier, Defendant obtained premarket approval for a predecessor device back in 1984, and on July 7, 2006, the FDA granted premarket approval of the particular spinal cord stimulator involved in this case. The parties further agree that by virtue of this FDA approval, the federal government has established requirements applicable to Defendant's spinal cord stimulator. *See Riegel,* 552 U.S. at 322-23, 128 S. Ct. at 1007 (recognizing that the premarket approval process mandated for Class III devices necessarily imposes federal requirements upon the specific device addressed in this process). This leaves only the question whether Plaintiff's product liability claims rest upon requirements that "relate to the safety or effectiveness of [Defendant's] device" and are "different from, or in addition to," the requirements imposed on this device by the federal government. 21 U.S.C. § 360k(a). If so, these claims are preempted.

As the Supreme Court has emphasized, the MDA's express preemption provision "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case parallel, rather than add to, federal requirements." *Riegel,* 552 U.S. at 330, 128 S. Ct. at 1011 (internal quotation marks and citations omitted). In her response to Defendant's motion, Plaintiff suggests that her product liability claims are properly viewed as "parallel" in this sense — that is, they rest upon Defendant's alleged breach of state-law duties derived from FDA regulations that prohibit the distribution of adulterated or misbranded products and establish Current Good

Manufacturing Practices ("CGMPs") that apply to all FDA-regulated medical devices. Because Plaintiff's first amended complaint identifies a whole host of FDA regulations and CGMPs that Defendant allegedly violated, (*see* First Amended Complaint at ¶¶ 53-76), Plaintiff contends that she has pled "parallel" claims of product liability that avoid express preemption.

Defendant challenges the adequacy of Plaintiff's pleading on two fronts. First, Defendant points to cases broadly holding that the FDA's CGMPs "are simply too generic, standing alone, to serve as the basis for" a parallel product liability claim that survives the MDA's express preemption provision. *In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation,* 592 F. Supp.2d 1147, 1157 (D. Minn. 2009), *aff'd,* 623 F.3d 1200 (8th Cir. 2010); *see also Horn v. Boston Scientific Neuromodulation Corp.,* No. CV409-074, 2011 WL 3893812, at *8-9 (S.D. Ga. Aug. 26, 2011); *Ilarraza v. Medtronic, Inc.,* 677 F. Supp.2d 582, 588 (E.D.N.Y. 2009). As one court has reasoned:

> . . . [The CGMPs] are intended to serve only as an umbrella quality system providing general objectives medical device manufacturers must seek to achieve. These regulations are purposefully broad so as to apply to a broad range of medical devices. The regulations are to be tailored by each manufacturer of a device to apply to [its] particular safety and efficacy needs. The intentionally vague and open-ended nature of the regulations relied upon is the precise reason why they cannot serve as the basis for a parallel claim. Since these regulations are open to a particular manufacturer's interpretation, allowing them to serve as a basis for a claim would lead to differing safety requirements that might emanate from various lawsuits. This would necessarily result in the imposition of standards that are "different from, or in addition to" those imposed by the MDA — precisely the result that the MDA preemption provision seeks to prevent. Accordingly, where, as here, a plaintiff relies on nothing more tha[n] CGMP[]s in support of a parallel cause of action, preemption bars the claim.

Ilarraza, 677 F. Supp.2d at 588 (internal quotation marks and citations omitted).

Yet, as Defendant acknowledges — albeit only in a footnote — the Sixth Circuit has

squarely rejected the notion that a violation of a CGMP can ***never*** serve as the basis for a parallel claim that avoids express preemption. *See Howard v. Sulzer Orthopedics, Inc.,* No. 09-3406, 382 F. App'x 436, 440 (6th Cir. June 16, 2010). The plaintiff in that case, Brian Howard, asserted product liability claims against Sulzer Orthopedics, the manufacturer of a knee implant that failed when it was used in Howard's body. Although Sulzer adhered to an FDA-approved process in manufacturing this medical device, it determined after complaints from thousands of patients that this process "left lubricating machine oil on the implants" during manufacture, resulting in an implant that "failed to bond with the [patient's] bone." *Howard,* 382 F. App'x at 438. Howard contended that Sulzer's failure to remove the lubricating oil from its knee implants during its manufacturing process constituted a violation of the FDA's CGMPs, but Sulzer pointed to the district court's decision in *In re Medtronic, supra,* 592 F. Supp.2d at 1157, as precluding Howard's reliance on the CGMPs as a basis for his product liability claims.

The Sixth Circuit held that one of Howard's product liability claims could go forward, explaining that the decision in *In re Medtronic* was distinguishable:

> [T]he alleged violations in [*In re Medtronic*] were different from the ones here; and moreover the plaintiff there did not even identify a specific GMP that he thought had been violated. Howard, in contrast, has done that; and, as we explain below, the particular GMP that he cites is not so vague as to be incapable of enforcement. We thus reject Sulzer's argument that the relevant GMP is categorically unenforceable here.

Howard, 382 F. App'x at 440. In particular, Howard cited a CGMP providing that "[w]here a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount

that does not adversely affect the device's quality." 382 F. App'x at 440 (quoting 21 C.F.R. § 820.70(h)). The Sixth Circuit observed that the lubricating oil used in Sulzer's manufacturing process "falls within the definition of manufacturing material" that Sulzer was obligated under the CGMP to remove from its medical device, and it concluded that Howard's product liability claim withstood preemption as a parallel claim resting on Sulzer's alleged violation of a sufficiently specific and enforceable CGMP. 382 F. App'x at 440-41.

As Defendant correctly observes, the Sixth Circuit's unpublished decision in *Howard* is not binding on this Court, and Defendant tersely suggests that *Howard* should be rejected as "wrongly decided." (Defendant's Motion, Br. in Support at 21 n.10.) The Sixth Circuit is not alone, however, in holding that a manufacturer's violation of a CGMP may serve as the basis for a parallel state-law claim that survives express preemption. In *Bausch v. Stryker Corp.,* 630 F.3d 546, 555 (7th Cir. 2010), for example, the Seventh Circuit opined that there was no "sound legal basis" for distinguishing between claims resting on "general requirements" such as CGMPs and claims derived from alleged violations of "concrete, device-specific requirements." The court explained:

> Section 360k makes preemption a defense if a state seeks to impose on a manufacturer "any requirement — (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). We emphasize the phrase "any requirement." And federal law is clear: for manufacturers of Class III medical devices, the Quality System Regulations and Current Good Manufacturing Practices adopted by the FDA under its delegated regulatory authority are legally binding requirements "under this chapter." 21 C.F.R. § 820.1. "The failure to comply with any applicable provision in this part [of the regulations] renders a device adulterated under section 501(h) of the [FDCA]. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action." 21 C.F.R. § 820.1(c).
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> Defendants' proposed distinction between concrete, product-specific

> requirements and more general requirements would also leave injured patients without any remedy for a wide range of harmful violations of federal law. The FDA regulations contain many requirements that are not concrete or product-specific, yet which are obviously vital to producing safe and effective medical devices. For example, the regulations require each manufacturer to "establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality," 21 C.F.R. § 820.70(e), and to "establish and maintain procedures for the use and removal" of manufacturing material (such as lubricants or abrasives, or cleaning and disinfectant agents) "to ensure that it is removed or limited to an amount that does not adversely affect the device's quality." 21 C.F.R. § 820.70(h). If a patient were harmed by an implanted hip replacement system that was contaminated, for example, by a production worker's blood or mucus or by a lubricant or abrasive that caused an infection after implantation, that contamination would present a substantial claim for violating requirements that are not "concrete" and "product-specific," yet which surely are essential for the manufacture of safe and effective medical devices for implantation in the human body.

Bausch, 630 F.3d at 555 (citation omitted). Accordingly, the Seventh Circuit concluded that the defendant manufacturer's suggested distinction between general regulations and product-specific requirements lacked support in either "the language of the [MDA's] preemption provision or . . . its purpose, to provide preemption for medical device manufacturers to the extent they actually comply with stringent requirements of federal law." 630 F.3d at 556; *see also Bass v. Stryker Corp.,* 669 F.3d 501, 511-12 (5th Cir. 2012) ("The key distinction between complaints that are sufficient to withstand a motion to dismiss and those that are not is not reliance on CGMPs, but rather the existence of a manufacturing defect caused by a violation of federal regulations *and* allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury."); *Raab v. Smith & Nephew, Inc.,* 150 F. Supp.3d 671, 692 (S.D. W. Va. 2015) (reasoning that "[v]iolations of the CGMP requirements are undoubtedly violations of federal law," and concluding that "CGMP-premised claims are not expressly preempted simply

because they rely on those regulations"); *Cline v. Advanced Neuromodulation Systems, Inc.,* 921 F. Supp.2d 1374, 1381 (N.D. Ga. 2012) (finding that a claim avoided express preemption where the plaintiff "provide[d] more than conclusory assertions of CGMP violations," but "also allege[d] specific facts about when and how these violations occurred in the manufacture of the specific device at issue"); *Gelber v. Stryker Corp.,* 788 F. Supp.2d 145, 159 (S.D.N.Y. 2011).

This Court is persuaded by the reasoning in *Howard* and *Bausch* that a plaintiff's reliance on violations of CGMPs in support of a product liability claim does not categorically dictate the express preemption of that claim. Rather, in determining whether such a claim is preempted, the key questions are (i) whether the plaintiff has identified specific CGMPs that the defendant device manufacturer has allegedly violated, *see Howard,* 382 F. App'x at 440, and (ii) whether the plaintiff's allegations, accepted as true, demonstrate that the plaintiff was injured as a result of the manufacturer's breach of a CGMP-based duty, *see Bass,* 669 F.3d at 512; *Cline,* 921 F. Supp.2d at 1381-82. Accordingly, the Court rejects Defendant's contention that Plaintiff's product liability claims should be dismissed as expressly preempted due to their reliance on CGMPs as the source of the legal obligations giving rise to those claims.

Yet, even accepting that Plaintiff may look to the FDA's CGMPs in support of parallel product liability claims that avoid express preemption, Defendant nonetheless insists that the allegations of Plaintiff's first amended complaint are insufficient to establish the requisite causal connection between Defendant's violation of a specific CGMP and a resulting device defect that brought about Plaintiff's injury. As Defendant observes, Plaintiff's first amended complaint does not focus on only one or a small handful of CGMPs that Defendant

allegedly violated in manufacturing the medical device at issue. Rather, over the course of nine pages and nearly thirty paragraphs, Plaintiff recites a plethora of CGMPs and other regulatory provisions to which Defendant allegedly was subject as it manufactured, distributed, and otherwise exercised control over this device. (*See* First Amended Complaint at ¶¶ 47-73.) A number of courts have rejected this "laundry list" approach to pleading a parallel claim arising from a manufacturer's alleged violation of FDA regulations or CGMPs. *See, e.g., Ali v. Allergan USA, Inc.,* No. 12-115, 2012 WL 3692396, at *10-*11 (E.D. Va. Aug. 23, 2012); *Ilarraza,* 677 F. Supp.2d at 588-89; *Parker v. Stryker Corp.,* 584 F. Supp.2d 1298, 1301-02 & n.5 (D. Colo. 2008).

Likewise, the allegations that follow Plaintiff's lengthy recitation of purportedly relevant CGMPs and regulatory duties are too vague and conclusory to satisfy the *Twombly/Iqbal* standard of plausibility. Plaintiff asserts "[u]pon information and belief" that Defendant's medical device "failed to meet" the performance standards and other requirements established in the FDA regulations, and that Defendant "failed to establish and maintain" the appropriate CGMPs governing the manufacture and testing of its device. (First Amended Complaint at ¶¶ 74-76.) Plaintiff then alleges that "[a]s a result of Defendant's failure to establish and maintain" the proper CGMPs, its "medical device was defective and resulted in injuries to Plaintiff." (*Id.* at ¶ 77.) As the courts have emphasized, a plaintiff "cannot simply incant the magic words '[the defendant manufacturer] violated FDA regulations' in order to avoid preemption." *In re Medtronic,* 592 F. Supp.2d at 1158; *see also Swisher v. Stryker Corp.,* No. 14-0028, 2014 WL 1153716, at *2 (W.D. Okla. March 14, 2014) ("[M]ore is required to make out a parallel claim than conclusory statements that a defendant violated multiple regulations."); *Desai v. Sorin CRM USA, Inc.,* No. 12-2995,

2013 WL 163298, at *6 (D.N.J. Jan. 15, 2013) (finding that the plaintiff's proposed amended complaint lacked any factual allegations "as to how [the defendant] allegedly violated federal regulations in its design or manufacture of" the device at issue); *Parker,* 584 F. Supp.2d at 1302 (explaining that the plaintiff's complaint did not "provide any factual detail to substantiate th[e] crucial allegation" that the defendant's manufacturing processes failed to comply with one or more FDA regulations). Nor can a plaintiff rely on conclusory allegations alone, without any supporting factual details, to plead the requisite causal connection between the defendant's alleged violation of FDA regulations and a device defect that resulted in the plaintiff's injury. *See, e.g., Ali,* 2012 WL 3692396, at *11-*12; *White v. Stryker Corp.,* 818 F. Supp.2d 1032, 1039-40 (W.D. Ky. 2011); *Ilarraza,* 677 F. Supp.2d at 588-89; *Horowitz v. Stryker Corp.,* 613 F. Supp.2d 271, 282-83 (E.D.N.Y. 2009). As in these other cases, the allegations put forward by Plaintiff here in support of her product liability claims lack the factual content necessary to permit the plausible inferences (i) that Defendant violated one or more FDA regulations in the manufacture of its spinal cord stimulator, and (ii) that Plaintiff was injured as a result of these violations.

In an effort to overcome these pleading deficiencies, Plaintiff seeks to supply the requisite specificity in her response to Defendant's motion.[4] In particular, Plaintiff contends that her product liability claims qualify as parallel, and thus avoid express preemption under the MDA, by virtue of their reliance on Defendant's violation of a specific CGMP that

[4]Notably, Plaintiff does not request in her response brief that she be granted leave to further amend her complaint in order to more clearly specify the regulatory violations that give rise to her product liability claims. Rather, she contends that the allegations of her first amended complaint already identify these violations in sufficient detail to preclude the dismissal of her product liability claims. (*See* Plaintiff's Response Br. at 22-23.)

provides as follows:

> Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.

21 C.F.R. § 820.70(h). Plaintiff further cites the commentary accompanying the FDA regulation that defines "manufacturing material," in which the FDA explains that "some components, such as natural rubber latex, contain allergenic proteins that must be reduced or removed from the finished devices." 61 Fed. Reg. 52,602, 52,610 (Oct. 7, 1996). As Plaintiff observes, the Sixth Circuit relied on the "manufacturing material" regulation and the FDA's accompanying commentary in *Howard,* 382 F. App'x at 440-41, concluding that the plaintiff in that case had stated a parallel product liability claim that withstood preemption through his allegations that the defendant manufacturer violated this regulation by failing to remove the lubricating oil used in the manufacture of its medical device. In Plaintiff's view, her allegations in this case likewise should be deemed sufficient to sustain her parallel product liability claims against Defendant, where the CGMP set forth in 21 C.F.R. § 820.70(h) purportedly imposed upon Defendant the obligation to remove any natural rubber latex from its spinal cord stimulator before this device was implanted in a patient.

As Defendant correctly observes, however, the CGMP that dictates the removal of potentially harmful manufacturing material does not assist Plaintiff in her attempt to plead parallel product liability claims, because the silicone rubber found in Defendant's spinal cord stimulator cannot be characterized as "manufacturing material" subject to this CGMP.

The pertinent FDA regulation defines manufacturing material as "any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer." 21 C.F.R. § 820.3(p). Yet, as illustrated by the public documents in the record describing Defendant's spinal cord stimulator, the silicone rubber in this device is not a "residue or impurity," but instead is expressly identified as among the materials that make up the device's connector block, grommets, and seals. (Plaintiff's Response, Ex. 1, PrimeAdvanced Neurostimulator Implant Manual at 8.) Consequently, the rubber in Defendant's device is present "by design or intent of the manufacturer," and not as "a residue or impurity." 21 C.F.R. § 820.3(p). As such, the rubber cited by Plaintiff as allegedly triggering her allergic reaction is not "manufacturing material" that must be removed or limited under the CGMP; rather, it fits comfortably within the regulatory definition of a "component," which encompasses "any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device." 21 C.F.R. § 820.3(c).

To be sure, the commentary accompanying the regulatory definition of "manufacturing material" cites "allergenic proteins" in "natural rubber latex" as an example of a "concomitant constituent" that must be reduced or removed from a device at the conclusion of the manufacturing process. 61 Fed. Reg. 52,602, 52,610 (Oct. 7, 1996). In Plaintiff's view, this comment supports a reading of the "manufacturing material" CGMP as mandating that Defendant remove all natural rubber latex from its spinal cord stimulator. (*See* Plaintiff's Response Br. at 18, 22.) At best, however, the FDA's commentary indicates

that the allergic proteins contained in natural rubber latex would qualify in some circumstances as a "residue or impurity" generated in the manufacturing process that must be reduced or removed in accordance with the CGMP. This limited example does not overcome the distinction, as expressly drawn in the FDA's definition of manufacturing material, between a "residue or impurity" and a substance that is present in a device "by design or intent of the manufacturer." 21 C.F.R. § 820.3(p).

Nothing in Plaintiff's first amended complaint suggests that the manufacturing process used by Defendant generated any such allergenic proteins as a residue or impurity that was subject to removal under the CGMP. Nor has Plaintiff alleged that her injuries resulted from a residue or impurity that Defendant failed to remove at the conclusion of its manufacturing process. To the contrary, the manual for Defendant's spinal cord stimulator expressly discloses that parts of this device contain silicone rubber or silicone medical adhesive, (*see* Plaintiff's Response, Ex. 1, PrimeAdvanced Neurostimulator Implant Manual at 8), and the intentional use of these materials in Defendant's device disqualifies them from consideration as "manufacturing materials" that must be reduced or removed from the device. Accordingly, Plaintiff has failed to allege a violation of an FDA regulation or CGMP that could support a parallel product liability claim that avoids preemption under the MDA.

Finally, even assuming that Plaintiff's allegations were sufficient to establish a violation of the CGMP that requires the reduction or removal of certain manufacturing materials, it bears emphasis that this alleged violation would support only Plaintiff's manufacturing defect theory of product liability, and would not save her design defect and failure to warn claims from express preemption. As Defendant points out, Plaintiff has alleged no facts indicating that the design of the device implanted in her deviated in any respect from the

design approved by the FDA as part of its premarket approval process for Class III medical devices. Accordingly, to prevail under a design defect theory, Plaintiff "would need to establish that [Defendant's] [d]evice should have been designed in a manner different than that approved by the FDA." *Beavers-Gabriel v. Medtronic, Inc.,* 15 F. Supp.3d 1021, 1040 (D. Haw. 2014); *see also Aaron v. Medtronic, Inc.,* No. 13-301, __ F. Supp.3d __, 2016 WL 5242957, at *9 (S.D. Ohio Sept. 22, 2016); *Hafer v. Medtronic, Inc.,* 99 F. Supp.3d 844, 861 (W.D. Tenn. 2015). As a number of courts have explained, such a "common law tort claim that presupposes a Class III device should have been designed in a manner other than that contemplated by its premarket approval is . . . expressly preempted by the MDA as interpreted by *Riegel.*" *Walker v. Medtronic, Inc.,* 670 F.3d 569, 580 (4th Cir. 2012); *see also In re Medtronic,* 623 F.3d at 1206; *Aaron,* __ F. Supp.3d at __, 2016 WL 5242957, at *9-*10; *Hafer,* 99 F. Supp.3d at 861; *Beavers-Gabriel,* 15 F. Supp.3d at 1040.

Plaintiff's failure to warn claim is expressly preempted on essentially the same grounds. Plaintiff has not alleged that the specific device implanted in her lacked the warning label approved by the FDA in the premarket approval process. This theory of recovery, therefore, depends upon a showing that the FDA-approved warnings were inadequate, and that Defendant was required under Michigan product liability law to provide additional warnings beyond those required by the FDA. Yet, the Supreme Court has emphasized that the MDA "[s]urely . . . would preempt a jury determination that the FDA-approved labeling for a [device] violated a state common-law requirement for additional warnings." *Riegel,* 552 U.S. at 329, 128 S. Ct. at 1011; *see also In re Medtronic,* 623 F.3d at 1205; *Aaron,* __ F. Supp.3d at __, 2016 WL 5242967, at *7; *Hafer,* 99 F. Supp.3d at 860. This is especially true where the FDA-approved labeling for Defendant's spinal cord

stimulator expressly warns of the possibility that "the implanted materials could cause an allergic or immune system response." (Defendant's Motion, Ex. C, User Manual at 23.)[5] Accordingly, the Court concludes on this additional ground that Plaintiff's design defect and failure to warn claims are expressly preempted.[6]

B. Plaintiff Has Sufficiently Pled Each Element of a State-Law Claim of Fraud.

Apart from her three product liability claims, Plaintiff also has asserted a claim of fraud, alleging that Defendant made misrepresentations to her that its spinal cord stimulator was safe for use by patients such as Plaintiff with known allergies to rubber and latex. In its present motion, Defendant seeks the dismissal of this claim for failure to allege one of the required elements of a viable claim of fraud: namely, that Defendant, through its representatives, made its alleged misrepresentations either with knowledge that they were false or with reckless disregard for their truthfulness. The Court disagrees, finding that Plaintiff's allegations are sufficient to satisfy this element of her claim of fraud.

To sustain a claim of fraud under Michigan law, a plaintiff must establish each of the following elements:

> (1) the defendant made a material representation; (2) the representation was false; (3) when the defendant made the representation, the defendant knew that it was false, or made it recklessly, without knowledge of its truth as a positive assertion; (4) the defendant made the representation with the intention that the plaintiff would act upon it; (5) the plaintiff acted in reliance upon it; and (6) the

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[5]As noted earlier, in resolving Defendant's Rule 12(b)(6) motion, the Court may properly consider the FDA-approved label for Defendant's device as a public record, even though this label was not expressly incorporated into Plaintiff's pleadings.

[6]In light of the Court's determination that Plaintiff's product liability claims are expressly preempted under the MDA's preemption provision, the Court need not address Defendant's contention that these claims are impliedly preempted by the FDCA.

plaintiff suffered damage.

M&D, Inc. v. McConkey, 231 Mich. App. 22, 585 N.W.2d 33, 36 (1998). Defendant challenges the third of these elements, contending that Plaintiff has offered only "conclusory allegations" that Defendant "had knowledge of other patients having allergic reactions to manufacturing materials and/or components" of its spinal cord stimulators," but nonetheless advised Plaintiff that "implanting the Spinal Cord Stimulator in patients with a latex and rubber allergy was safe and would not cause an allergic reaction." (Defendant's Motion, Br. in Support at 25 (quoting First Amended Complaint at ¶¶ 44, 111).) In Defendant's view, these allegations do not suffice to establish that its representatives had the requisite state of mind when they allegedly advised Plaintiff that Defendant's device was safe despite her allergies to latex and rubber.

The Court cannot agree. As Plaintiff observes, while "a party must state with particularity the circumstances constituting fraud or mistake," this same Federal Rule provides that "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Thus, a plaintiff "must plead facts about the defendant's mental state, which, accepted as true, make the state-of-mind allegation plausible on its face." *Republic Bank & Trust Co. v. Bear Stearns & Co.,* 683 F.3d 239, 247 (6th Cir. 2012) (internal quotation marks and citation omitted). In this case, Plaintiff's complaint recounts several meetings prior to the implantation of Defendant's device at which she (i) informed Defendant's representative, Violet, that she had latex and rubber allergies, (ii) specifically inquired whether other patients had experienced allergic reactions to the manufacturing materials or components used in Defendant's spinal cord stimulator, and (iii) was told in response that there had been no such reports of allergic reactions and

that latex and rubber allergies did not preclude the use of Defendant's device. (*See* First Amended Complaint at ¶¶ 18-21, 24, 25.) Plaintiff further alleges that after Defendant's device was implanted in her and she developed a severe allergic reaction, she contacted Violet and was "only then informed . . . that other previous patients had indeed had allergic reactions to manufacturing materials and/or components of" Defendant's spinal cord stimulators. (*Id.* at ¶ 29.)

These allegations, accepted as true, support a plausible inference that Defendant's representative knowingly or recklessly provided false assurances to Plaintiff about the safety of implanting Defendant's device in patients with allergies to rubber or latex. According to the complaint, within a few days after Defendant's device was implanted in Plaintiff, Defendant's representative acknowledged her awareness that other patients had developed allergic reactions to the manufacturing materials or components used in this device. (*See id.*) It surely is plausible to infer that this representative did not suddenly become aware of these prior instances of allergic reactions, but that she instead had knowledge of these reactions when she met with Plaintiff just a few days earlier, on the date of the procedure to implant Defendant's device, and reiterated her claim that no other patients had experienced allergic reactions to Defendant's spinal cord stimulators. (*See id.* at ¶ 25.) These specific allegations that Defendant's representative denied a material fact one day, only to admit this same fact just a few days later, are sufficient to raise an inference that Defendant's representative had the requisite knowledge that she was not being truthful when she assured Plaintiff that Defendant's device was safe for those with rubber or latex allergies. It follows that Plaintiff may go forward with her claim of fraud.

IV. CONCLUSION

For these reasons,

The Court hereby GRANTS IN PART AND DENIES IN PART Defendant's motion to dismiss Plaintiff's first amended complaint. (Dkt. 17.) More specifically, the Court DISMISSES Counts I, II, and III of the first amended complaint, but Plaintiff may proceed with the fraud claim asserted in Count IV of her first amended complaint.

SO ORDERED.

s/Nancy G. Edmunds
Nancy G. Edmunds
United States District Judge

Dated: April 18, 2017

I hereby certify that a copy of the foregoing document was served upon counsel of record on April 18, 2017, by electronic and/or ordinary mail.

s/Carol J. Bethel
Case Manager